BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

67. (New Claim) A composition of claim 60 wherein the carrier component is a saline solution.

68. (New Claim) A composition of claim 60 which is ophthalmically acceptable.

REMARKS

The above-identified application has been carefully reviewed in light of the Examiner's communication mailed November 19, 2001. Enclosed is a Request for Extension of Time, and required fee, extending the period for responding to the Examiner's communication to and including April 19, 2002.

Claims 1 to 35 have been canceled, without prejudice. Applicant expressly reserves the right to seek patent protection based upon these claims or similar claims in one or more later filed related applications.

New claims 36 to 68 have been added and are directed to embodiments for which patent protection is sought. These new claims are presented to address certain of the rejections raised by the Examiner under 35 USC 112, for example, with regard to original claims 13, 14 and 20; to incorporate subject matter from one or more of the previous dependent claims into certain of the new independent claims; to more clearly define the present invention and to facilitate prosecution of the above-identified application. Overall, the new claims are not more narrow in scope than the canceled claims. Therefore, applicant submits that the rule in the Festo case does not apply in the current circumstance.

Original claims 13, 14 and 20 were rejected under 35 USC 112, second paragraph. The subject matter of these original claims have been substantially incorporated into claims new 48, 49 and 53, respectively. These new claims have been written to address the rejections of claims 13, 14 and 20. Applicant submits that these new claims satisfy the requirements of 35 USC 112, second paragraph. Therefore, applicant requests that the rejection under

35 USC 112, second paragraph, as it relates to the subject matter of new claims 48, 49 and 53, be withdrawn.

Original claims 1, 8 to 11, 16, 19, 26, 27 and 31 have been rejected under 35 USC 112, second paragraph. The Examiner contends that the term "derivatives" is indefinite because by that term known and yet to be discovered compounds are claimed. Applicant traverses this rejection as it pertains to new claims 36, 43 to 46, 51, 52, 59, 60 and 64, which includes subject matter similar to original claims 1, 8 to 11, 16, 19, 26, 27 and 31, respectively.

The present specification, at page 18, defines the term "derivatives" specifically as it relates to derivatives of cyclodextrin. However, it is clear from this definition that the term "derivatives", as set forth in the above-identified application, in general means any substituted or otherwise modified materials that have the characteristic chemical structure of the material recited in the claims sufficiently to function as the recited material.

The Examiner is correct that the term "derivatives" may encompass both known and yet to be discovered compounds. However, the nature of the present invention is such that the yet to be discovered compounds, if any, encompassed in the present claims are encompassed only to the extent that they are employed in the present multi-component compositions. Applicant is entitled to claim the present compositions in such a manner to obtain patent protection for the full, patentable scope of the invention. Applicant does not intend to claim any yet to be discovered material itself. However, materials, whether presently available or yet to be discovered, which perform in accordance with the present invention are encompassed within the present claims to the extent that such materials perform or function in the present multi-component compositions.

In view of the above, applicant submits that the term "derivatives" does not render the present claims, and in particular

claims 36, 43 to 46, 51, 52, 59, 60 and 64, indefinite under 35 USC 112, second paragraph.

The Examiner contends that claims 1 and 26 are unclear because of the term "substantially". Applicant traverses this contention as it relates to new claims 36 and 59, which include subject matter similar to original claims 1 and 26, respectively.

Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning. York Products, Inc. v. Central Tractor Farm and Family Center, 40 USPQ 2d 1619, 1622 (Fed. Cir. 1996); Hoganas AB v. Dresser Industries, Inc., 28 USPQ 2d 1936, 1938 (Fed. Cir. 1993); Smithkline Diagnostics, Inc. v. Helena Lab. Corp., 8 USPQ 2d 1468, 1471 (Fed. Cir. 1988); ZMI Corp. v. Cardiac Resuscitator Corp., 5 USPQ 2d 1557, 1560 (Fed. Cir. 1988). Ordinarily "substantially" means "considerable in... extent" American Heritage Dictionary, Second Collage Edition, 1213 (2d Ed. 1982) or "largely but not wholly that which is specified," Webster's Ninth New Collegiate Dictionary, 1176 (9th ed. 1983). York Products, Inc. v. Central Tractor Farm and Family Center, supra.

With regard to the phrase "the complex remaining substantially intact in an aqueous environment", as set forth in claims 36 and 59, the above-identified application discloses no novel use for the word "substantially". Thus, applying the ordinary meaning to the word "substantially" in the phrase "the complex remaining substantially intact in an aqueous environment" means that a large portion of the complexes in the present compositions, but not necessarily all of the complexes in the present compositions, remain intact in an aqueous environment.

In view of the above, applicant submits that the term "substantially" as used in the present claims 36 and 59, particularly points out and distinctly claims the subject matter which applicant regards as the invention sufficiently to satisfy 35 USC 112, second paragraph.

In summary, applicant submits that the present claims, that is claims 36 to 68, particularly point out and distinctly claim the subject matter of the invention under 35 USC 112, second paragraph. Therefore, applicant respectfully requests that any rejection of the present claims under 35 USC 112, second paragraph be withdrawn.

The Examiner has provisionally rejected claims 1 to 35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 23 of copending application Serial No. 09/848,249.

Since application Serial No. 09/848,249 has not yet been issued as a patent, applicant submits that the above-noted double patenting rejection is premature. However, applicant is willing, if the copending application is issued with claims which render the claims in the above-identified application subject to an obviousness-type double patenting rejection, to file a proper terminal disclaimer and required fee to overcome this double patenting rejection.

In view of the above, applicant requests that the Examiner hold the obviousness-type double patenting rejection in abeyance pending the outcome of the prosecution of the copending application.

Claims 1 to 4, 6 to 9, 11, 12, 26 to 28 and 29 have been rejected under 35 USC 102(b) as being anticipated by Hanssler et al. Claims 1, 2, 6 to 9, 11, 12, 25, 27 and 31 have been rejected under 35 USC 102(b) as being anticipated by FR 2272684 (hereinafter referred to as "French"). Claims 1, 2, 6 to 9, 11, 12, 25, 27 and 31 have been rejected under 35 USC 102(b) as being anticipated by JP 62048618 (hereinafter referred to as "Japan"). A copy of an English translation of each of these foreign language references is submitted herewith in the SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT.

Applicant submits that each of these rejections is inappropriate and not properly based with regard to the previous

claims, which have been canceled, without prejudice. In addition, applicant submits that each of these rejections is inappropriate and not properly based with regard to the new claims. Applicant respectfully requests the Examiner to consider the following comments as they relate to the rejections and the new claims.

The present claims are directed to compositions including a therapeutic component and an efficacy enhancing component present in a complex with the therapeutic component. The present compositions provide surprising and substantial benefits, for example, enhanced benefits, certain of which are recited in the present claims.

In new independent claim 36, the compositions comprise a therapeutic component in a therapeutically effective amount and an efficacy enhancing component, present in a complex with the therapeutic component, in an effective amount to enhance the pharmacokinetic disposition of the therapeutic component and to at least one of (1) enhance the movement of the therapeutic component across a lipid membrane and (2) enhance the movement of the therapeutic component across a biological membrane under physiological conditions. The efficacy enhancing component is selected from anionic polymers, fatty acids, derivatives thereof and mixtures thereof. The complex, for example, an ion pair complex, remains substantially intact in an aqueous environment, that is the complex remains substantially as a single stiochiometric entity in an aqueous environment.

In new independent claim 59, the compositions comprise an adrenergic agonist and a fatty acid selected from docosahexanoic acids, linolenic acids, derivatives thereof and mixtures thereof. The agonist is present in a complex with the fatty acid and the complex remains substantially intact in an aqueous environment.

In independent claim 60, the present compositions comprise a complex and a carrier component. The complex comprises a therapeutic component and an efficacy enhancing component selected from anionic polymers, fatty acids, derivatives thereof

and mixtures thereof. The efficacy enhancing component is effective to at least one of (1) enhance the movement of the therapeutic component across a lipid membrane and (2) enhance the movement of the therapeutic component across a biological membrane under physiologic conditions.

Both new independent claims 36 and 60 include substantially the subject matter of original claims 17 and 18. Claims 17 and 18 have not been rejected based on any of Hanssler et al, French and Japan. For this reason alone, applicant submits that new independent claims 36 and 60 are not anticipated by and are unobvious from and patentable over Hanssler et al, French and Japan, taken singly or in any combination under 35 USC 102(b) and 103(a).

In addition, none of Hanssler et al, French and Japan disclose, teach or suggest the invention as set forth in new independent claims 36 and 60. For example, none of Hanssler et al, French and Japan disclose, teach or even suggest any complex of an efficacy enhancing component with a therapeutic component, let alone the complexes recited in the present claims. Moreover, none of the prior art even suggest such complexes including an efficacy enhancing component in an amount effective to enhance the pharmacokinetic disposition of the therapeutic component, as recited in new independent claim 36. Further, none of Hanssler et al, French and Japan even suggest an efficacy enhancing component in a complex in an amount effective to at least one of (1) enhance the movement of a therapeutic component across a lipid membrane and (2) enhance the movement of a therapeutic component across a biological membrane under physiological conditions, as recited in both new independent claims 36 and 60.

As noted above, independent claims 36 and 60 include subject matter from original claims which have not been rejected by the Examiner. In addition, the prior art, that is Hanssler et al, French and Japan, do not even suggest the enhanced benefits of the present compositions recited in new independent claims 36 and 60.

Moreover, the prior art provides no motivation or incentive to one of ordinary skill in the art to produce the present compositions and obtain the benefits of the present compositions, for example, the enhanced benefits recited in independent claims 36 and 60.

In view of the above, applicant submits that new independent claims 36 and 60 are not anticipated by and are unobvious from and patentable over Hanssler et al, French and Japan, taken singly or in any combination, under 35 USC 102(b) and 103(a).

New independent claim 59 includes substantially the same subject matter as original independent claim 26. Original independent claims 26 was rejected as being anticipated by Hanssler et al under 35 USC 102(b).

Hanssler et al discloses combinations with fungicidal activity containing a known fungicide and a vegetable oil or a lecithin or lineolic acid.

Hanssler et al does not disclose, teach or suggest the invention set forth in new independent claim 59. For example, Hanssler et al does not even suggest an adrenergic agonist and a fatty acid, let alone that the adrenergic agonist is present in a complex with the fatty acid and that the complex remains substantially intact in an aqueous environment, as recited in independent claim 59.

In view of the above, applicant submits that new independent claim 59 is not anticipated by Hanssler et al under 35 USC 102(b).

Moreover, by teaching the presence of a fungicide and not disclosing, teaching or even suggesting adrenergic agonists, Hanssler et al actually teaches away from the present invention as set forth in new independent claim 59. Hanssler et al provides no motivation incentive to one of ordinary skill in the art to produce the compositions as recited in new independent claim 59, let alone to do so and obtain the substantial benefits from such compositions achieved by applicant.

In view of the above, applicant submits that new independent claim 59 is not anticipated by and is unobvious from and patentable over Hanssler et al under 35 USC 102(b) and 103(a).

As noted above, new independent claim 59 includes subject matter from original claim 26 which has not been rejected as being anticipated by French and Japan. For this reason alone, applicant submits that new independent claim 59 is not anticipated by French and Japan under 35 USC 102(b).

In addition, neither French nor Japan discloses, teaches or suggests the present invention as recited in new independent claim 59. For example, neither French nor Japan even suggests a composition comprising an adrenergic agonist and a fatty acid wherein the adrenergic agonist is present in a complex with the fatty acid and the complex remains substantially intact in an aqueous environment, as recited in new independent claim 59. Further, neither French nor Japan, or any combination of these two references, provides any motivation or incentive to one of ordinary skill in the art to form compositions recited in new independent claim 59, let alone to do so and obtain the substantial benefits achieved by applicant.

In view of the above, applicant submits that new independent claim 59 is not anticipated by and is unobvious from and patentable over French, Japan and any combination thereof under 35 USC 102(b) and 103(a).

Each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art, taken singly or in any combination, disclose, teach or even suggest the present compositions including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims, that is claims 36 to 68, satisfy the requirements of 35 USC 112, and are not anticipated by and are unobvious from and

patentable over the prior art under 35 USC 102 and 103. Therefore, applicant submits that the present claims are allowable and respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Respectfully submitted,

Frank J. Uxa
Attorney for Applicant
Reg. No. 25,612
4 Venture, Suite 300
Irvine, CA 92618
(949) 450-1750
Facsimile (494) 450-1764